SURVEILLANCE OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 WITH DUAL P16/KI-67 IMMUNOCYTOCHEMISTRY STAINING. TRIAL PROTOCOL AND PRELIMINARY REPORT

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Introduction/Background Cervical intraepithelial neoplasia (CIN) grade 2 is considered a high-grade squamous intraepithelial lesion requiring surgical treatment. Excisional cervical procedures, though, have been linked to an increased risk of preterm birth in subsequent pregnancies. Therefore, and given the fact that the vast majority of CIN2 cases will regress, there is a tendency to avoid surgical treatment for women who wish fertility preservation. The aim of the CIN2DIN study is to determine the diagnostic accuracy of P16/Ki-67 immunocytochemistry (ICC) for the timely detection of CIN3 +, among women with untreated CIN2, compared to cytology.

Methodology According to the study design, women with biopsy confirmed CIN2, after written informed consent, will be subjected to cervicovaginal sampling for p16/Ki-67 ICC (CINtec PLUS, Roche laboratories AG, Mannheim, Germany), cytology and high-risk Human Papillomavirus (hrHPV) testing (cobas® HPV Test, Roche Molecular Systems, Pleasanton, CA, USA) (t=0). After six months (t=1), participants will be subjected to colposcopy, and, cervicovaginal sampling for cytology and p16/Ki-67 ICC. After 12 months (t=2) participants will be subjected to colposcopy, and, and cervicovaginal sampling for hrHPV testing, cytology and p16/Ki-67 ICC. Participants will be also examined after 18 and 24 months (t=3, t=4, respectively). Examinations at t=3 and t=4 will be similar to t=1, and t=2 respectively. All women after visit t=4 exit the study and are referred to treatment according to the local guidelines.

Results To date 5 women with biopsy proven CIN2 have been recruited. Those women have been subjected to pap test, hrHPV testing, and p16/Ki-67 ICC.

Conclusion The CIN2DIN study is original and innovative. So far, no studies have been conducted on the value of P16/Ki-67 ICC for CIN2 surveillance. If the study identifies high correlation of P16/Ki-67 ICC to colposcopy, larger studies could be designed to investigate longer-term reassurance for the surveillance of women with untreated CIN2 without colposcopy.

Disclosures The authors have nothing to disclose.

#145 INTERNATIONAL VARIATIONS IN POST-OPERATIVE MORBIDITY AND MORTALITY FOLLOWING GYNAECOLOGICAL ONCOLOGY SURGERY (GO SOAR1)

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Introduction/Background Gynaecological malignancies affect women in low and middle income countries (LMICs) at disproportionately higher rates compared with high income countries (HICs), but little is known about global variations in access, quality and outcomes in gynaecological oncology surgery between LMIC and HIC settings.

Methodology Multicentre, international prospective cohort-study of women undergoing surgery for primary ovariectomy/uterosalpingo cervix/vulva/vagina/gestational trophoblastic malignancies (NCT04379861). Multilevel logistic-regression determined relationships within three-level nested models of patients within hospitals/countries.

Results We enrolled 1820 patients from 73 hospitals in 27 countries (1078 (59.2%) high income countries, 453 (24.9%) upper middle income countries, 174 (9.6%) lower middle income countries, 115 (6.3%) low income countries). Mean follow-up was 58.7 and 55.7 days from date of surgery in LMICs/HICs respectively. Overall-morbidity (Clavien-Dindo IV) for all tumour-groups was 34.7% (233/672) and 33.5% (338/1009), whilst mortality 2.1% (14/672) versus 1% (10/109) for LMICs/HICs respectively. Minor-morbidity (Clavien-Dindo I-II) for all tumour-groups was 26.5% (267/1009), whilst major-morbidity (Clavien-Dindo III-V) 8.2% (55/672) and 7% (71/1009) for LMICs/HICs respectively. Higher minor-morbidity was associated with previous laparoscopic surgery (OR=1.435, 95%CI=1.046–1.966, p=0.025), COVID-19 positive status (OR=5.025, 95%CI=1.262–20.008, p=0.022), pre-operative mechanical bowel preparation (OR=1.474, 95%CI=1.054–2.061, p=0.023), longer surgeries (OR=1.253, 95%CI=1.066–1.472, p=0.006), greater blood loss (OR=1.274, 95%CI=1.081–1.502, p=0.004), and occurrence of intra-operative complication (OR=2.03, 95%CI=1.498–3.241, p<0.001). Minimal-access-surgery was protective against minor-morbidity (OR=0.522, 95%CI=0.371–0.735, p=0.001). Higher major-morbidity was associated with longer surgeries (OR=1.37, 95%CI=1.128–1.664, p=0.002), greater blood loss (OR=1.398, 95%CI=1.175–1.664, p=0.001), and seniority of lead-surgeon with junior surgeons three times more likely to have a major-